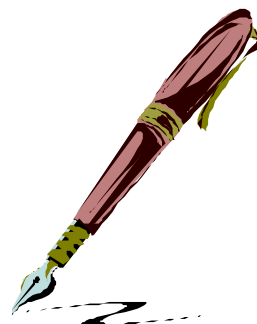


Beltsville Area Guidelines for Laboratory Notebooks



Beltsville Area Laboratory
Notebook, Revised 11/17/99



Table of Contents

Acknowledgment	iii
Forward	iv
I. Introduction	1
II. Experimental Notebook	2
A. Responsibility	2
B. Type of Notebook	2
III. Suggested Guidelines for Maintaining Notebooks	2
A. Types of entries	3
B. Table of Contents	3
C. List of acronyms, abbreviation, terms, and trademarks	3
D. Organization of experimental entries	3
E. General rules.	4
IV. Cross-referencing	5
V. Considerations in Record-Keeping for Future Patent Applications	5
A. What to Record	6
B. Witnessing	6
C. Dates	6
VI. Collaboration and Sensitive Materials	6
A. Partnerships	7
B. Sensitive Materials	7
VII. Storage of data and notebooks	7
A. Short-term storage	7
B. Long-term storage	8
Appendix A	9
Appendix B	10

Acknowledgment

The BA Record-Keeping Task Force would like to acknowledge Dr. John Cherry, Director of the Eastern Regional Research Center, and his committee on record-keeping for developing the “Employee Laboratory Notebook Protocol”. This protocol provided guidance to our committee and many of the concepts covered by the document were incorporated into the current guidelines.

Forward

Good record-keeping is fundamental to the practice of science. Without carefully recorded descriptions of experimental design, conditions, and results, laborious and expensive research may go to waste. Documentation is especially critical when intellectual property is at stake, such as when a discovery is potentially patentable. It is not uncommon for ARS to be asked by regulatory agencies for raw data upon which published conclusions are based. With the advent of computerization of laboratory instruments, and a variety of electronic forms in which data may be kept, issues of record-keeping have proliferated; a simple notebook is no longer the only or even the primary place that much research data are kept. Finally, while rare, allegations of fraud occasionally arise; a well-kept notebook is a good defense against such allegations.

In order to address issues concerning proper laboratory record-keeping I appointed a Task Force to recommend policy on this subject. The following document is the culmination of their efforts as modified by input from scientists and research leaders throughout the Beltsville Area. I would like to emphasize that these are guidelines and situations may arise that are not directly covered by this document. Questions concerning proper record-keeping in a specific situation should be taken up with your supervising SY or RL to ensure that accurate and complete record-keeping is achieved. It is the responsibility of each SY to ensure that all laboratory notebooks and related research documentation are maintained properly. I hope all of you will take the time to read the document carefully and implement the recommended guidelines in your laboratories.

Phyllis E. Johnson
Beltsville Area Director

I. Introduction

The purpose of this document is to provide researchers with a general guide for maintaining laboratory records. The following guidelines are not meant to be all-inclusive. With the wide variety of research being conducted under the ARS umbrella, no single set of guidelines can cover all possible situations. The guidelines presented in this document are written to be as comprehensive as possible, but it is the responsibility of individual researchers to exercise their judgment concerning specific situations. It is the responsibility of each career scientist to ensure that all members of the laboratory maintain their respective laboratory notebooks and other records in a manner that, (1) accurately documents the research undertaken, (2) is comprehensive enough to allow others to unambiguously interpret and reproduce the experiments, (3) provides all the necessary information for publications to be prepared, and (4) protects any patent positions resulting from the research.

The laboratory notebook, whether handwritten or electronic, is a factual record of the progress of scientific investigations. As such, the laboratory notebook is distinct from a logbook, which is strictly a chronological listing of events, such as the handling of samples, instrument usage, equipment performance, etc., and a diary or personal journal, which is basically a synopsis of each day's work and may contain personal insights and opinions. The information written into the laboratory notebook is used for several purposes, most importantly, to preserve the experimental data, and to record observations and interpretations integral to any scientific investigation.

Accurate documentation of your research serves several functions. In addition to providing a written record of how the research was conducted, the laboratory notebook and other associated records also form the basis of all patent applications. Improperly maintained records can impede the ability of ARS to write and file patents. Of even greater importance is the role a notebook can play in the defense of a challenge to a patent application or issued patent. The legal community has very strict guidelines concerning what constitutes an adequately maintained and witnessed notebook. Failure to adhere to these rules can result in the loss of a patent.

Adequately maintained notebooks and records can also guard against any accusations of unethical scientific behavior. Even Nobel laureates can be embroiled in investigations concerning the authenticity of data. The best defense against accusations of scientific fraud is a well-maintained notebook, preferably read and witnessed by a fellow scientist not directly involved in the research.

Notebooks also can serve to accurately determine the respective contributions to the research by various members of a laboratory. This can be very useful in determining whether an individual meets the ARS requirements for authorship and for resolving disputes about the order of authorship on manuscripts. For this, and the other reasons addressed above, it is very important that all members of the laboratory understand the fundamental criteria for maintaining a laboratory notebook and associated records and implement these guidelines on a daily basis.

Researchers also must understand that laboratory notebooks and data generated while working for ARS are government property. As such, all notebooks and related materials must remain with ARS after termination of employment. As government documents, the materials are accessible to the public through the Freedom of Information Act. Although this does not occur often, it is another reason to adequately maintain your laboratory notebooks. With a little extra effort directed at maintaining good laboratory notebooks, many unnecessary problems can be avoided.

II. *Experimental Notebook*

As a guiding principle, the notebook, whether handwritten or electronic, should contain sufficient detail and clarity that another scientist could pick up the notebook at a later date and successfully repeat the work, making the same observations that were originally recorded. In addition, the laboratory notebook should enable progress report and manuscript preparation and protect any patent positions resulting from the research.

A. Responsibility

It is the responsibility of each career scientist to ensure that laboratory notebooks and related research documentation are maintained in an appropriate manner. This includes ensuring that support personnel involved in the research are adequately trained and supervised in note-keeping. Career scientists can delegate the duty *but not the responsibility* for maintaining research documentation. It is the support person's responsibility to ensure that these protocols are followed and to inform the career scientist if any difficulties arise.

B. Type of Notebook

1. Hardbound. The main laboratory notebook should be a bound notebook with serially numbered pages. An example is the official green-cover ARS notebook. Official ARS notebooks are available through Central Supply from the Warehouse in Landover, MD (phone #- 301/436-4219). They may be obtained by ordering cat. # ARS-1. Other types of bound, serially numbered notebooks may be used provided their covers have the same information recorded on them as the official ARS notebook. For reference, a copy of the ARS laboratory notebook cover is shown in Appendix A. There may be instances where it is necessary to use loose-leaf notebooks for data storage. For example, the storage of computer printouts or spectra too voluminous to attach to the main notebook can be stored in loose-leaf notebooks. Some data may be stored on floppy disks or other magnetic media. However, these other notebooks and electronic media should be appropriately cross-referenced from the main notebook (see section entitled Cross-referencing).

2. Electronic. Although electronic notebooks are now becoming commercially available, if these types of notebooks are used as the primary or sole laboratory notebook, software must be chosen with care. Use of a word processing program will not provide unalterable date-stamping of entries as is done by electronic notebook software, so word processing software is not suitable. Electronic notebooks are still in the developmental stages and may not be considered legally acceptable for patent purposes.

III. *Suggested Guidelines for Maintaining Notebooks*

The following guidelines are not meant to be all-inclusive. They are meant to serve as a general outline for maintaining a laboratory notebook. Again, it is the responsibility of each career scientist to ensure that all members of the laboratory maintain their respective laboratory notebooks in a proper manner.

A. Types of entries

- The hypothesis being tested, experiments--materials, procedures/protocols, results, significance, interpretation. Note: always record raw data, not just data in its final form. Record experiments that do not work as well as those that do.
- Ideas for future experiments, new research projects, etc.
- The content and date of phone conversations with colleagues should be documented if they concern ongoing or potential future research projects and collaborations particularly if patents or CRADAs are a possibility.
- Relevant literature citations.
- The content of brainstorming sessions with members of your laboratory, research unit, or collaborators. This may be important at a later date for determining the start date of a patent application.
- CRADA issues.
- Explanations of lapses in time during the course of an experiment. This is important if you are pursuing something which may be patentable. A long lapse can make it appear that you have “abandoned” the patent. Since U.S. patents are based on “first discovery” not “first to file,” this is occasionally a critical point.
- Manuscript tracking.
- Safety issues.

B. Table of Contents

Each laboratory notebook should include a Table of Contents that lists the title of each experiment and the date it was started.

C. List of acronyms, abbreviation, terms, and trademarks

A list of acronyms, abbreviations, terms, trademarks, etc., should appear at the front or back of the notebook. Remember, someone else should be able to reproduce your work based on your notes, but first they must be able to understand what you’ve recorded.

D. Organization of experimental entries

1. Title and date
2. Introduction/rationale/purpose
What the experiment is, why it is being conducted, and who is actually doing the work.
3. Procedure/experimental plan/materials and methods
 - Give a concise, detailed description of the experimental protocols to ensure that experiments can be reproduced independently by others.
 - Record vendors, catalog numbers, lot numbers, purity, concentrations, and expiration dates of important reagents (sometimes unknown impurities are the cause of your observation!)
 - Give details of the origin of special reagents such as plasmid DNA, RNA, seeds, cuttings, cell lines, etc.
 - Record information describing animal (or plant) model chosen and why; strain, sex, age of animals, feed used, treatments and how they were administered.

- Give details concerning the collection of specimens, how they were stored, processed, and analyzed.
 - Record make, model, serial number, settings, calibrations, etc., of instruments used in obtaining data.
 - List individuals involved in the work and their respective contributions.
4. Results
- Include raw data or cross-reference to where raw data are stored.
 - Record data in its original unmanipulated form.
 - Analysis of data should include a description of any and all transformations, calculations, or other mathematical manipulations used to process raw data.
 - Reference any computer programs used to manipulate or analyze data including the date and version of the software.
5. Conclusions/discussion/significance/follow-up experiments
- Discuss findings that are positive and/or negative.
 - Discuss significance of the findings.
 - Discuss any insights obtained from the results.
 - Discuss thoughts on future plans and experiments for the project.
 - Avoid using terminology indicating abandonment of the project. This can make the work unpatentable.
 - Do not comment on whether an idea or result can be patented. This can make the work unpatentable.
 - If the experiment is proof of “reduction to practice” clearly indicate so. This is often critical for patent purposes.

E. General rules.

- Use a bound notebook for information not recorded in electronic form.
- Have a different notebook for each project.
- Use indelible ink.
- Write legibly.
- Use pages sequentially.
- Date each page.
- Explain gaps in time between experiments (vacation, working on other projects, etc.).
- Mark out blank pages.
- Cross out and date all changes.
- Reference earlier pages for continuity of experiments.
- Permanently affix all labels, photos, diagrams, etc.
- Give each affixed item an identifier (Exp. #, date).
- For large amounts of data such as computer printouts, separate 3-ring binders may be maintained but clear, accurate dating and cross-referencing is necessary.
- Raw data measurements must be retrievable from the notebook or via cross-reference with another source.
- Summary statistics maintained in a notebook are not a substitute for raw data.
- Negative results as well as positive results should be recorded.

- All pages should be signed, dated, and witnessed for patent purposes. Witnessing is not required if the research is not likely to be patentable. However, witnessing, even if not done daily, can also be helpful if it is necessary to defend a scientific ethics/fraud allegation, since it attests to the fact that records were made on the dates they say they were.
- Cross-referencing of electronically stored data in another file or physical location is also necessary.

IV. Cross-referencing

Although it is highly recommended that all information and raw data be permanently recorded in your laboratory notebook, there may be instances when cross-referencing to other sources is warranted. Keeping clear and accurate references will help ensure the reproducibility of your experiments and may provide additional corroborating evidence when patent or other issues arise.

Types of information to cross-reference:

- Hard copies of electronic data are recommended whenever possible; however, information stored on computers such as greenhouse instrumentation, gel documentation systems, or other media should be cross-referenced when hard copies cannot be routinely generated. It is also important to cross-reference formats and software programs you may be using.
- Physical samples stored in freezers or other storage facilities should be clearly labeled and referenced.
- Cross-referencing to publications or protocols you are using in your experiments is also recommended.
- Printouts, diagrams or other raw data too voluminous to put in your notebook should be maintained in a separate notebook that is clearly cross-referenced to the corresponding experiment. You should also cross-reference any previous pages or notebooks pertinent to your present experiment.
- Many researchers maintain a notebook of Standard Operating Procedures (SOPs) used in their laboratories. These protocols/procedures should also be cross-referenced in your notebook. Any modifications to the SOP should be documented.
- Logbooks of instrumentation (i.e., centrifuges, rotors, model #, etc.) used in your experiment should be referenced in your notebook.
- Any journals or diaries of phone or personal communications with collaborators or customers should be recorded or referenced in your notebook.

V. Considerations in Record-Keeping for Future Patent Applications

It is very important for each inventor to maintain good clear documentation providing evidence of the dates of creation of various aspects of the invention. This is important because in the United States, *it is first to invent or conceive the idea* who has sole entitlement to a patent whereas in the rest of the world it is first to file. A laboratory notebook will suffice as corroborating evidence of the date of invention if it has sufficient guarantees of trustworthiness. Many patent attorneys do not encourage electronic storage of information as the sole source of documentation. Alteration of information and dates can occur and go undetected. If electronic information and data storage are used, hard copies should be printed,

affixed to a notebook and witnessed. While unbound records are acceptable for a patent examiner, it is preferable to have all information in a bound notebook if conflicts should arise between two parties over patent application and rights.

A. What to Record

- Record all research and development efforts including ideas and “think tank” sessions. This may be important later in determining a “true” start date for a patent application
- Clearly differentiate different parts of an experiment and different experiments. This may help in the patent application and for patent examination.
- Periodically summarize past results and future plans for the research. This is important in establishing the chronological profile.
- Interpret the data in the book. If an experiment fails, it should still be documented with comments regarding the reason for the failure. Draw conclusions regarding the results. Avoid opinions regarding patentability of the contents of the study.
- Procedures, data entry, etc should be meticulously entered.

B. Witnessing

- A witness should be a person familiar with the work, but a non-inventor. While technicians may be classified as non-inventors initially, they may take on enough of a role to be classified as inventors later. Thus, it is best to not use a technician or assistant. Remember, witnesses may be called to testify that they were not involved in the project.
- A witness should examine the write-ups for clarity, continuity, proper dating, proper cross-referencing, etc.
- Witness promptly – preferably once a week. This process can be expedited by organizing groups of individuals for regular meetings to witness each others notebooks.

C. Dates

- Record dates when an idea was formed and when work on the idea was started and completed.
- Details and results should be promptly entered and dated.
- Notebook entries should be witnessed promptly. The witness should sign and date every page reviewed on the date reviewed.

VI. *Collaboration and Sensitive Materials*

Moving research results out of the laboratory and into the hands of users is sometimes most effective when partnerships are formed. These partnerships can be via Memoranda of Understanding (MOU), Cooperative Research and Development Agreements (CRADAs), grants, and other agreements. Intellectual property rights must be decided before entering into such agreements and may impact the record-keeping process. Attention to sensitive materials to avoid inappropriate disclosures also warrants special record-keeping methods. Classified materials and maintenance of personal privacy are two examples. Research with classified materials may also warrant a separate record-keeping notebook to separate these materials from other related research.

A. Partnerships

- Decide on intellectual property rights before entering into agreements. Maintain notebooks with this in mind.
- Strict delineation of records pertaining to work on an agreement versus related work not conducted under the agreement is advisable to avoid grounds for partners claiming all work conducted by an investigator.
- Access the CRADA website for further details:
www.ars.usda.gov/afm2/ppweb/141-01.htm
- Access information on specific cooperative agreements, grants, etc., from the area office. (Agency web sites are not available at this time).

B. Sensitive Materials

- Access the following web site for details on classified materials:
www.ars.usda.gov/afm2/ppweb/253-01.HTM. If questions arise contact the Classified Materials Control Officer.
- Note that classified materials require special security containers for daily and long-term storage.
- Be aware of the sensitive nature of data/samples, etc. and how privacy may be maintained if a record notebook is to be accessed in the future by others.
- Note that information that may be linked to an individual or an individual's land, thereby violating privacy laws, requires a means of preserving privacy. For example, geographic/site specific information about farm conditions, production (yield, production capacity, etc.) can be considered proprietary and may be used in the future to determine real estate prices or as a decision making criterion for crop insurance.

VII. Storage of data and notebooks

A. Short-term storage

- Alternatively, data and notebooks should be stored in a dry, cool area that is not located near water or heat sources.
- Electronically stored data should be treated in a similar manner but also must be protected from equipment that may generate magnetic fields.
- Placing notebooks and other forms of data into sealed plastic bags prior to storage can help minimize the chances of water damage.
- Backup copies of electronic data should be stored in a physically separate location.
- Magnetic media for electronic data storage have relatively short life spans, and are not suitable for long term storage. Furthermore, software and/or hardware used to write electronic data may become obsolete and therefore, inaccessible for future reading. Use generic formats and media whenever possible to ensure future access to the information. Make sure that magnetic media is written using a device that has been properly maintained. This will insure that any other device of the same type can read the data..
- Charts, graphs, and equipment readouts should be stored at least until the data are published. After publication, such materials may be archived (see below) if the lead scientist determines that retention of this material is not necessary.

B. Long-term storage

- Notebooks and data not needed for reference purposes or in support of patents should be archived.
- Notebooks and other forms of data in support of a patent should be stored in a secure place for the life of the patent. These notebooks should be clearly identified as containing data in support of a patent and the patent # should be written on the cover of the notebook or other documentation.
- Materials to be archived should be sent to the nearest Federal Records Center. For the Washington D.C. area, this is the Washington National Records Center (WNRC) located in Suitland, MD. The agency has a Web site which includes information on the facility and is located at www.nara.gov/nara/dc/wnrc.html#agencies.
- Procedures for retiring records can be found at the Web site www.ars.usda.gov/afm2/divisions/itd/RecMgmt/recmgmt.htm under “How do I retire records to the Washington National Records Center”.
- Form SF 135 must be completed and submitted prior to shipping records for archiving. Additional information is available in the “Guide to Washington National Records Center Services” that describes Form SF 135 and instructions for completing it.
- Further inquiries can be directed to Stephen Pollard, REE Records Officer, at (202) 720-3359.
- Currently, materials are archived for 25 years. After 25 years, they are reviewed by “competent scientific or technical personnel” and may be disposed of if deemed no longer needed for current research.
- Each laboratory should keep a record of all notebooks archived.
- It is recommended that, whenever possible, data should be published prior to archiving.



Agricultural
Research
Service

United States
Department of
Agriculture

Official ARS Laboratory Notebook

Notebook No. _____

Name _____

Location _____

CRIS Project No. _____

Title _____

Dates Used: From _____ **To** _____

Appendix B
Abbreviated Guidelines for Good Record-Keeping

- **For complete details on procedures to follow in recommended use of the laboratory notebook refer to the BA Guidelines for Laboratory Notebooks.**
- **Visit with your supervisor regarding appropriate procedures and actions to follow in keeping good laboratory records in the notebook.**
- ✓ Use the official green ARS notebook if at all possible. Otherwise ensure that a bound notebook is used. Use a different notebook for each project.
- ✓ Develop a Table of Contents including the title of the experiment and the date it was started.
- ✓ Give each experiment a unique title and indicate the date that it was started.
- ✓ Enter the procedures, experimental plan, methods and protocol in a clear and concise manner to ensure that other researchers can reproduce the findings.
- ✓ Enter raw data in original form. Describe any transformations/manipulations to data.
- ✓ Large amounts of data may be stored in 3-ring binders if clear, accurate dating and cross-referencing are provided.
- ✓ Discuss the significance of the findings and any insights obtained from the results.
- ✓ Use indelible ink. Make sure all entries are legible.
- ✓ Use pages sequentially and date each page.
- ✓ Mark out blank pages. Cross out and date all changes.
- ✓ Reference earlier pages for continuity of experiments.
- ✓ Permanently affix all labels, photos, diagrams, etc. Each affixed item should have an identifier written on it.
- ✓ Record vendors, catalog numbers, lot numbers, purity, concentrations and expiration dates and origin of important reagents and experimental material.
- ✓ Record detailed background material on experimental/biological material.
- ✓ Provide details regarding the collection, storage, processing and analysis of specimens.
- ✓ Record make, model, serial number, setting, calibrations, etc. of instruments used in obtaining data.
- ✓ Follow standardized safety procedures. Note any safety issues arising in experiments.
- ✓ Devise and follow a plan to have notebooks witnessed.
- ✓ Notebooks should be stored in a dry, cool area protected from water and heat sources.
- ✓ Whenever possible, make hard copies of all electronically stored data. Backup copies of electronic data should be stored in a physically separate location.

--